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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,185	12/14/2000	Danny Charles Bowman	2552-011	9139

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EXAMINER

GAKH, YELENA G

ART UNIT PAPER NUMBER

1743

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/737,185	BOWMAN ET AL.	
Examiner	Art Unit	
Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,38 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21,38 and 40-44 is/are rejected.
- 7) ☒ Claim(s) 1,5,9,17-21,38 and 40-44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/15/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The RCE with preliminary amendment filed on 01/06/04 is acknowledged. Claim 39 is cancelled. Claims 1-21, 38 and 40-44 are pending in the application.

Claim Objections

2. Claims 1, 9, 17 and 19 are objected to because of the following informalities: claims 1, 9 and 17 recite "**a** members" on line 4; claim 19 recites "distributing population members **to at** a specimen collection facility". Appropriate correction is required.

Claims 5, 17-21, 38 and 40-44 use a mixed terminology, i.e. a "vessel" and a "container". A uniform usage of one term is required for clarification of the language and providing antecedent basis for the limitations in the claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites providing three containers located at three different locations. It is not clear from the claim the way it is written if these containers have anything in common, or they are three different containers; in the latter case, it is not clear, what is the essence of the step of providing three containers at different locations?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 36-41 and 44** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129B1).

Petrick teaches a method and business form for establishing a chain of custody, which comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206). This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other

data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57).

6. **Claims 1, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are

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recited in the claims indicated above. "A population of" biomedical specimen collection with "members" located at various locations of the specimen path is an intrinsic feature of the invention.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 5, 8 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick.

Although Petrick did not specifically disclose storing data including the identity of a supplier of the container (vessel?) and its product information, it would have been obvious for anyone of ordinary skill in the art to include this information along with other data in Petrick's specimen system, because vessels (containers) from different suppliers may vary, and therefore such information is important for handling them properly, and because information on a supplier is always conventionally provided with products.

11. **Claims 16, 17, 20, 38, 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick in view of Hoffman et al. (US 5,613,012).

Although Petrick does not particularly teach encoding electronic signature in the electronic tag, she specifically indicates "tester's signature" in form 102, Fig. 3B.

Since Petrick indicated that all forms can be filled manually or electronically, it would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman for securing electronic transactions, because this is an obvious improvement over hand-written document and because electronic submission of the forms suggested by Petrick assumes electronically encoded signature.

Response to Arguments

12. Applicant's arguments with respect to claims 1-21, 38 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.

Yelena G. Gakh
1/7/04

A handwritten signature in cursive script, appearing to read 'Yelena Gakh', written in dark ink.